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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
760-12 DIV/CON/RCE

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Typed or printed name Barbara Thomas

Application Number	Filed
10/630,562	July 30, 2003

First Named Inventor
Scott Smith

Art Unit	Examiner
3774	Suba Ganasan

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 41,321
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34

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October 8, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

HELICALLY FORMED STENT/GRAFT ASSEMBLY
Application No.: 10/630,562 // Confirmation No.: 8643
Request dated October 8, 2008 // Final Office Action dated July 9, 2008
Docket No.: 760-12 DIV/CON/RCE

Introduction

Claims 1-9 and 11-13 are pending. Claims 2, 4, 5, 9-11 are withdrawn from consideration. Claims 1, 3, 6-8, 12 and 13 have been rejected in an Office Action dated July 9, 2008 and marked final.

Summary of the Independent Claim

Independent claim 1 is directed to a stent/graft composite device formed from a flat preformed planar strip and stent assembly. The stent/graft composite device comprises an elongate preformed non-textile planar strip of polymeric graft material having a first exterior surface and a second opposed luminal surface; and a planar stent attached onto one of said opposed flat exterior or luminal surfaces of said strip to form said flat strip assembly, said strip assembly being helically wound into a continuous tubular structure. (emphasis added)

For the reasons set forth below, Appellants respectfully that the applied references fails to teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent. Moreover, forming the flat strip assembly and then helically winding the assembly strip to form the inventive stent/graft composite device offers structural advantages over the prior art as described in the Specification at paragraphs [0010] and [0054]

Section 103 Rejections

Claims 1, 3, 6-8, 12 and 13 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,352,561 to Leopold et al. (hereinafter "Leopold") in view U.S. Patent No. 6,165,210 to Lau et al. (hereinafter "Lau"). Applicants respectfully traverse.

Leopold is directed to a stent-graft 106. (Leopold, column 6, lines 37-38; FIG. 3). The stent-graft 106 of Leopold includes a stent 126, a luminal graft 124 and an outer covering or tape member 128. (Leopold, column 9, lines 9-15). The stent 126 is formed by helically

winding a wire around a mandrel. (Leopold, column 10, lines 63-65). Leopold then specifically teaches that the helically wound wire is heated while the wire is on the mandrel to set the shape, e.g.., tubular stent shape, of the so-formed stent. (Leopold, column 10, lines 65-67). Thus, Leopold specifically teaches that its tubular stent 106 is to be formed by winding the stent wire itself about the mandrel, and the so-formed tubular stent 106 does not yet have its luminal graft 124 or its outer tape member 128.

Leopold also forms its luminal graft 124 independently from its stent 106. (Leopold, column 11, lines 45-49). Leopold then specifically teaches that its luminal, tubular graft 124 is placed over a mandrel. (Leopold, column 11, lines 9-15). Leopold then teaches that its formed tubular stent 106 is placed over the tubular graft 124 so that both tubular devices are disposed over this mandrel. (Leopold, column 11, lines 49-53).

Finally, Leopold then wraps its tape member 28 over the exterior portions of the stent 106. (Leopold, column 11, lines 54-57). Leopold then places the mandrel into an oven to form its stent-graft 106. (Leopold, column 11, line 66, to column 12, line 7).

Thus, Leopold independently forms a tubular stent 106 and a tubular luminal graft 124, and its tape member 128 is to helically wrapped over these tubular components to form its tubular stent 106. In other words, Leopold clearly fails to teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent.

Moreover, such teachings of Leopold are not only in direct contrast to the present invention, but are also a teaching away from the structural limitations of the subject independent claim. For example, Leopold fails to teach or suggest, *inter alia*, an elongate preformed non-textile planar strip of polymeric graft material, a planar stent attached to the planar graft material to form a flat strip assembly, which is subsequently wound to form the inventive stent graft.

As the Examiner acknowledges that Leopold fails to teach or suggest, *inter alia*, a planar stent assembly, the Examiner applies Lau, in particular FIGS 6, 7, 9 and 10 of Lau. Lau does teach that its stent structure 200, 202 of FIGS. 6 and 7 may be formed from a flat sheet. (Lau, column 13, lines 19-20). Lau, however, specifically teaches that its preformed strips of stent materials are to be wound over a mandrel. (Lau, column 14, lines 42-51). After Lau's strips of stent material are helically wound over a mandrel, then its outer tubular graft or sleeve 217 is slipped over the helically wound stent 214. (Lau, column 14, lines 52-53; FIG. 10). Indeed, Lau specifically teaches throughout its patent that its tubular stent is to be first formed and then its graft layer is to be placed or formed over the tubular stent. (See, e.g., Lau, column 26, lines 48-58; column 27, lines 21-23; etc.).

Thus, Lau fails to teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent. Indeed, Lau specifically teaches away from the claimed flat strip assembly because Lau requires that a tubular graft or sleeve must be used to form its device. This is not only in direct contrast to the present invention, but is clearly a teaching away from the present invention.

Accordingly, Lau fails to cure the deficiencies of Leopold.

While the examiner alleges that claimed limitation of "said strip assembly being helically wound into a continuous tubular structure" to be a product-by-process limitation with no structural limitations, the examiner under this reasoning simply ignored the claimed structural limitations of independent claim 1. Clearly, Leopold and Lau individually fail to teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent.

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose

from a reference only so much that supports the alleged rejection. *Id.* It is only through hindsight reconstruction and selective picking and choosing while ignoring divergent teachings does the Examiner attempt to reach the present invention through the combination of Leopold and Lau. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993). Such hindsight reconstruction by the Examiner is clear as both Leopold and Lau individually fail to teach or suggest a planar stent and graft strip assembly.

Moreover, the Supreme Court addressed the standard for obviousness in its decision of *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. ___; 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 U.S.P.Q.2d 1385 (2007). In order for an examiner to establish a *prima facie* case of obviousness after *KSR*, some degree of predictability is necessary. (citation to be provided in the Appeal Brief, if necessary). *Takeda Chemical Industries Ltd. V. Alphapharm Pty. Ltd.*, 83 USPQ2d 1169 (Federal Circuit 2007) is a post *KSR* decision in which the Federal Circuit articulated standards for establishing non-obviousness which again includes predictability of success. (citation to be provided in the Appeal Brief, if necessary). Further, Section 2143.02 (II) of the MPEP states that "Obviousness does not require absolute predictability, however, at least some degree of predictability is required."

Clearly, the disclosures of Leopold and Lau do not provide sufficient predictability or expectation to support a *prima facie* case of obviousness as neither of these references disclose, teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent. As neither of these references disclose, teach or suggest the present invention, the examiner must provide some reasoning with some degree of predictability of success that one of ordinary skill in the art would modify Leopold and Lau in an attempt to arrive at the present invention. The expectation and predictability to arrive art the present invention though Leopold and Lau do not rise to a level that represents a *prima facie*

case of obviousness. It is only through impermissible hindsight reconstruction by using the subject application as a roadmap does the examiner attempt to present a *prima facie* case of obviousness.

Moreover, as the inventive stent/graft composite device is formed from a flat planar strip assembly of planar graft material and a planar stent, the resulting device is structurally improved over the prior art because the assembly components, i.e., planar graft and planar stent, may be more accurately positioned with respect to one and the other and better secured to each other to provide a stent/graft composite device with improved integrity, as described in the Specification at paragraph [00554].

Therefore, Leopold and Lau, individually or in combination, fail to teach or suggest the inventive stent graft, as set forth in independent claim 1 because Leopold and Lau fail to teach or suggest the claimed structural limitations of the claimed invention and fail to teach or suggest the improved tubular device of the present invention so formed from the claimed structural limitations.

Reconsideration and withdrawal of the rejection of claims 1, 3, 6-8, 12 and 13 under 35 U.S.C. §103(a) are respectfully requested.

Respectfully submitted,

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